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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,173	11/06/2003	Xi Chen	11134-013-999	4030
20583	7590	08/10/2006	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017				AULAKH, CHARANJIT
		ART UNIT		PAPER NUMBER
		1625		

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/705,173	CHEN ET AL.	
	Examiner	Art Unit	
	Charanjit S. Aulakh	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 17 July 2006.
- 2a) This action is FINAL.
- 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-52 is/are pending in the application.
 - 4a) Of the above claim(s) 3 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2 and 4-52 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>8/4/06</u> |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/15, 6/14, 6/8</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. According to paper filed on July 17, 2006, the applicants elected group I with traverse for further prosecution in response to restriction requirement. However, during a telephone conversation with the applicant's attorney on Aug. 4, 2006, it was found that there was a confusion regarding the value of variable Q. The examiner wrote the original restriction requirement based on the assumption that when Q represented – N(R)-(C1-C3)alkylene, -N(R)- group was substituted with C1-C3 alkylene group and therefore, Q-containing ring was always a 5-membered ring containing 1N atom. However, during a telephonic conversation with the applicant's attorney on Aug. 4, 2006, the attorney mentioned that when Q represented N(R)-(C1-C3)alkylene, alkylene group represents part of the ring and therefore, Q-containing ring can be a 6, 7 or 8-membered ring containing 1 N atom. Due to this confusion, an agreement was reached to rewrite the restriction requirement as following :

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 1-5 and 35-52, drawn to compounds of formula (I) where Q represents –N(R)-, pharmaceutical compositions containing these compounds and a method of using these compounds, classified in class 548, subclass 421.
 - II. Claims 1, 2 and 4-52, drawn to compounds of formula (I) where Q represents –N(R)-(C1) alkylene, pharmaceutical compositions containing these compounds and a method of using these compounds, classified in class 546, subclass 70.

III. Claims 1, 2, 4, 5 and 35-52, drawn to compounds of formula (I) where Q represents –N(R)-(C2-C3) alkylene, pharmaceutical compositions containing these compounds and a method of using these compounds, classified in class 540, subclass 476.

3. The inventions I, II and III as defined above are patentably distinct, each from the other since they are structurally so divergent that a reference showing compounds of invention I would not render compounds of inventions II or III *prima facia* obvious. Search required for e.g ; compounds of invention I in class 548 is not the same search required for e.g ; compounds of invention II in class 546 and therefore, constitutes a burdensome search.

4. During a telephone conversation with the applicant's attorney, Mr. Roger Rich on Aug. 4, 2006, a provisional election was made with traverse to prosecute the invention of group II, claims 1, 2 and 4-52. Affirmation of this election must be made by applicant in replying to this Office action. Claim 3 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 6-52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The following eight different factors (see *Ex parte Foreman*, 230 USPQ at 547; *Wands*, *In re*, 858.F. 2d 731, 8 USPQ 2d 1400, Fed. Cir. 1988) must be considered in order for the specification to be enabling for what is being claimed:

Quantity of experimentation necessary, the amount of direction or guidance provided, presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability and the breadth of claims. In the instant case, the specification is not enabling based on atleast four of the above mentioned eight different factors such as quantity of experimentation necessary, the amount of direction or guidance provided, presence of working examples, the state of the prior art, unpredictability and the breadth of claims.

In regard to making hydrates, solvates and prodrugs of instant compounds of formula II (claims 6-52), there is no teaching or guidance present in the specification for preparing specific hydrates, solvates and prodrugs. There is not even a single example present in the specification for preparing hydrates, solvates and prodrugs of instant compounds of formula II. There is lot of unpredictability regarding stability of hydrates and solvates of compounds in the art. Similarly, there is lot of unpredictability regarding

effectiveness of various forms of prodrugs following their in vivo administration. The instant compounds of formula II encompasses hundreds of thousands of compounds based on the values of variables R1, R2, R", L1, L2, X, Y, Z and n and therefore, in absence of such teachings, guidance, presence of working examples and unpredictability, it would require undue experimentation to select specific hydrates, solvates and prodrugs which will be stable and also effective following their in vivo administration.

In regard to using instant compounds of formula II (see claims 35-52) for treating various disease conditions, the specification mentions in example 80 on pages 92 and 93 that modulatory activity of instant compounds can be assessed using the in vitro and in vivo assay methods described above and furthermore, mentions that exemplary compounds demonstrated MCHR1 modulatory activity. However, there is no teaching in the specification whether the compounds are agonists or antagonists at MCHR1 receptors. The utility of instant compounds will be different based on agonist versus antagonist activity of instant compounds at MCHR1 receptors. There is no teaching or direction present regarding specific in vitro or in vivo assays for evaluating agonist versus antagonist activity of instant compounds at MCHR1 receptors. There are no working examples present showing efficacy of instant compounds in known in vivo or in vitro models of any disease condition including obesity, eating disorders, anxiety disorders and mood disorders. There is no teaching either in the specification or in the prior art regarding well known utility of structurally closely related compounds for treating any disease condition including obesity, eating disorders, anxiety disorders and

mood disorders. The instant compounds of formula II encompasses hundreds of thousands of compounds based on the values of variables R1, R2, R", L1, L2, X, Y, Z and n and therefore, in absence of such teachings, guidance, presence of working examples and the state of the prior art, it would require undue experimentation to evaluate agonist versus antagonist activity at MCHR1 receptors and to demonstrate the efficacy of instant compounds in known in vitro or in vivo models of various disease conditions including obesity, eating disorders, anxiety disorders and mood disorders and hence their utility for treating these disease conditions.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1, 2 and 4-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In independent claim 1, variable R1 is defined but is not present in formula (I). It appears that (Ar) group should be substituted with (R1)n and not (R)n. An appropriate correction is required.

In independent claim 1 (lines 42-46) and claim 6 (lines 91-95), variables R5-R18 are mentioned to contain R groups. However, according to the definition of these variables, these variables do not contain R group at all. The only variable which contains R group is variable Q in formula (I) in claim 1. An appropriate correction is required.

In independent claim 6, the terms --- hydrates, solvates and prodrugs --- are indefinite since specific hydrates, solvates and prodrugs are not defined.

In claims 41 and 50, the term –modulating --- is indefinite since it is not clear whether the MCHR is activated , inhibited or unchanged?

In claim 45, specific disorders or conditions mediated by MCHR are not defined.

Claim 15 recites the limitation "p is 1, 2 or 3" in claim 13. There is insufficient antecedent basis for this limitation in the claim.

10. Claims 1, 2, 4, 5 and 35-52 are objected for containing non-elected subject matter.

Allowable Subject Matter

11. The following is a statement of reasons for the indication of allowable subject matter:

The instant compounds directed to the elected subject matter are allowable over the prior art since they are neither disclosed nor obvious over the prior art. In the prior art, Chen (U.S. Patent 6,858,619) discloses fused heterocyclic compounds which are closely related to the instant compounds. However, the closely related compound (see example 10 in column 31) differs from the instant compounds in lacking instant variable Z and furthermore, there is no teaching or motivation in the prior art to modify the compounds of Chen to prepare the instant compounds.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor; Thomas McKenzie can be reached on (571)272-0670. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

C. S. Aulakh
Charanjit S. Aulakh
Primary Examiner
Art Unit 1625